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JULIA CHURCH DIERKER
DIERKER & ASSOCIATES, P.C.
3331 W. BIG BEAVER RD. SUITE 109
TROY, MI 48084-2813

EXAMINER	
ROZANSKI, MICHAEL T	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,261	THOMAS ET AL.	
	Examiner	Art Unit	
	MICHAEL ROZANSKI	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Applicant remarks, filed 7/21/08, with respect to preliminary amendment filed 8/19/04 that was not entered due to a PTO error have been fully considered and are persuasive. The non-final Office action of 4/24/08 has been withdrawn.

Information Disclosure Statement

Applicant is advised that copies of the non-patent literature referenced on the IDS of 2/11/04 have not been received.

Specification

The disclosure is objected to because of the following informalities:

1. The status of the continuing data on page 1 of the specification is required to be updated.

2. The submitted specification contains irregularities (for example, see pg 12, line 23) that caused the transfer of the spec to the PG pub version to present typographical errors (see PG pub at [0052]). Applicant is advised to review the PG pub version for similar errors.

3. On pg 19, line 22, "inner wall 14" should be "inner wall 15". Applicant is advised to review the application to correct any other errors.

4. In the brief description of the drawings, Fig 2 is described as a view along "1-1" in figure 1, while figure 1 only has a "2-2." Applicant is advised to review the application to correct any other errors.

Appropriate correction is required.

Claim Objections

Claims 1, 3, 11, 12, 22, and 42 are objected to because of the following informalities:

In claim 1, line 14, the word "market" should be replaced by the word "marker".

In claim 1, line 15, in line 16-17, "the substance to be imaged" lacks antecedent basis.

In claims 11 and 22, it is unclear as to what other structural limitations have been set forth. The claims merely define the intended use of the device.

In claim 12, "the longitudinal plane" lacks antecedent basis.

In claim 42, "the step of verifying image registration" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 24, 26, and 30, it is unclear how the imaging material can be a CT or MR contrast agent or ultrasound imaging material when the respective

independent claims require the imaging material to be a radiopharmaceutical material that would be suitable for producing an image detectable by PET or SPECT. Does the imaging material have properties that would allow it to be imaged via particle emission-type imagers *and* other modalities such as MR and ultrasound?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-15, 17-23, and 26-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner (US Patent No. 5,154,179), in view of Filler (US Patent No. 5,948,384).

With regards to claims 1, 4, 7, 8, 14, 15, 20, 28, 32-34, Ratner discloses a

visibility enhancement device that is inserted into the body. The device comprises a flexible marker member with a lumen (fig. 3), which is composed of biological stable substance and is insertable into the body cavity (col.3, lines 50-64). The marker member comprises a proximal end (fig. 3, ref. 23), a distal end (fig. 3, ref. 24) and an interior portion (fig. 3, ref. 22c). An imaging material is retained into the marker member and it does not directly contact with the internal body (claim 9 and fig. 3).

With regards to claims 2, 3, 5, 12 and 31, Ratner discloses that the imaging material is injected into the marker member by using a catheter (fig. 3, ref.46). The imaging material is movably positioned and dispersed longitudinally in a homogeneous manner in the interior of the marker member. (col. 6, lines 19-25), (col. 10, lines 2-5) and (fig. 3).

With regards to claims 6, 13 and 29, Ratner discloses that the lumen is composed of biological stable material, which is capable of translating the detectable signal to give visual representation (col. 4, lines 24-34).

With regards to claims 9, 18, 19, 35 and 36, Ratner discloses that the marker member is composed of an interior lumen (fig.6, ref. 57) and an exterior lumen (fig.6, ref.56). The interior and exterior lumen defines a space in between and the imaging material is contained external to the interior lumen (fig.6) and also internal to the interior lumen (col. 7, lines 35-39).

With regards to claims 11 and 22, Ratner discloses that the device is adapted to be inserted into anatomical structures including urinary track (col. 8, lines 62-69).

With regards to claim 37, Ratner discloses that the interior lumen contained a

second distinct imaging material than the imaging material contained in the exterior lumen (co1.10, lines 24-46).

With regards to claim 17, Ratner discloses that the marker member contains imaging material that comprises a gel (col.6, lines 12-14).

Ratner discloses the invention describes above. Ratner also discloses that marker member can also contain different kinds of imaging materials (col. 9, lines 4-32). However, Ratner fails to disclose using a radiopharmaceutical material as imaging material that comprises radioisotopes and the marker member is detectable by single photon emission computed tomography detector.

Filler discloses diagnostic marker that are injected into the body. The marker includes radioisotopes that are detectable by using single photon emission computed tomography detector (col.3, lines 64-67). The markers are injected into the body using a catheter (col. 14, lines 14-19). Filler further discloses that the radioisotope produces a decay signal (col. 11, lines 9-14)in centimeter range (col. 14, lines 38-41), and emits gamma particles in the range between 30 KeV to 1000 KeV (col. 11, lines 47-54). Filler further discloses the use of MRI contrast agents (col. 25, lines 51-56). The MRI contrast agents are selected from the group consisting supermagnetic or paramagnetic compounds (col. 29, lines 48-50) and gadolinium compound (col. 8, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Ratner's visibility enhancement device and use radioisotopes that decays and are detectable by single photon emission computed tomography detector as taught by Filler for obtaining better image contrast.

Claims 10 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Filler as applied to claims 9 and 37 above, and further in view of Valley et al (US Patent No. 5,766,151).

Ratner and Filler discloses the invention described above. However, Ratner and Filler fail to disclose inflation of the interior lumen.

Valley discloses a catheter based system for the infusion of cardioplegic agent into the patient coronary arteries. The catheter based system comprises a catheter with interior inflating lumen, which delivers the inflation fluid and results in the inflation of the balloon (col. 8, lines 41-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use a catheter with inflating lumen as taught by Valley to inflate the lumen and blocks the blood flow of the veins in which the catheter is placed for obtainning better images during static motions in the veins.

Claims 16, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Filler as applied to claims 15 and 20 above, and further in view of Unger et al (US Patent No. 5,736,121).

Ratner and Filler disclose the invention described above. However, Ratner and Filler fail to disclose CT contrast agent. Unger discloses a contrast agent that can be used with computer tomography (abstract). The contrast agent comprises propylene

glycol (col. 14, lines 34-38) and iohexol (co1.30, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use the contrast agent disclose by Unger to be able to obtain images by using different contrast agents for obtaining improved diagnostic results.

Claims 39, 40, 41, 43, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner (US Patent No. 5,154,179), in view of Miller et al. (US Patent No. 6,226,418).

Ratner discloses the invention described above. However, Ratner fails to disclose registration of first and second image.

Miller discloses an apparatus and method for registering medical images. The method includes automatically landmark registration of the images that are acquired from PET or MRI image modalities (co1.6, lines 36-49). The registration step comprises registration of atleast two sequential images (col. 16, lines 39-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visualization device and include image registration to register images acquired from different image modalities as taught by Miller for obtaining better quality of images for advance diagnostic purposes.

With regards to claim 45, Ratner discloses an imaging material that is retained into the marker member and does not directly contact with the internal body (claim 9 and fig. 3). It would have been obvious to one of ordinary skill in the art at the time of

the invention to have further modified Ratner's visualization device and take PET images by using different contrast agent with different radionuclide and further register images as taught by Miller for acquiring results by using two different contrast agents for obtaining better imaging results.

Claims 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Miller as applied to claim 39 above, and further in view of Driscoll, Jr. et al. (US Patent No. 5,926,568).

Ratner and Miller disclose the invention described above. However, Ratner and Miller fail to disclose verification of image registration.

Driscoll discloses a method and apparatus for verifying identity using of image correlation. The method includes verifying image registration (col. 10, lines 33-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use verification of image registration as taught by Driscoll for precise acquisition of the data.

Claims 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Miller and Driscoll Jr. et al. as applied to claim 42 above, and further in view of Chaney et al. (US Patent No. 5,926,568).

Ratner, Miller and Driscoll Jr. et al. disclose the invention described above. However, Ratner, Miller and Driscoll Jr. et al. fail to disclose registration of the images.

Chaney discloses a method of registering radiotherapy images (col. 3, lines 36-

39). The method includes automatically registration of two images (col. 5, lines 63-68) by using image registration algorithm (col. 20, lines 32-34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use image registration method as taught by Chaney for obtaining high resolution images.

Claims 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Miller as applied to claim 39 above, and further in view of Engdahl et al. (US Patent No. 6,303,935).

Ratner and Miller disclose the invention described above. However, Ratner and Miller fail to disclose acquiring PET images by using two different radionuclides.

Engdahl discloses a combine PET/SPET nuclear imaging system. The imaging system obtains first and second images by using different radionuclide (col.3, line 56 to col. 4, line 6).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use image acquisition technique by using different radionuclide as taught by Engdahl for comparing the acquired images and obtaining the image with better quality.

Claims 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ratner in view of Miller as applied to claim 39 above, and further in view of Chaney et al. (US Patent No. 5,926,568).

Ratner and Miller disclose the invention described above. However, Ratner and Miller fail to disclose alignment of the images.

Chaney discloses a method of registering radiotherapy images (col. 3, lines 36-39). Chaney further discloses the alignment of subsequent images (col. 7, lines 7-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have further modified Ratner's visibility enhancement device and use image alignment method as taught by Chaney for obtaining high quality of images without distortion.

Response to Arguments

Applicant has requested an Office action responsive to the preliminary amendment filed 8/19/04, wherein the previous Office action was not responsive to the preliminary amendment. It appears that the amendment had not been previously entered due to PTO error. As such, this action is made Non-Final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

MR